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August 19, 1999

Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20857

**Citizen Petition**

Dear Sir/Madam:

The undersigned respectfully submits this petition under Section 502 of the Federal Food, Drug and Cosmetic Act ("FFDCA") and Section 10.25 of FDA's regulations on behalf of Ansell Healthcare Inc., a manufacturer of condoms and other medical devices.

**A. Action Requested**

This petition requests that FDA approve the use on individual condom packaging for both latex and non-latex condoms of a shortened version of the statement required for condoms containing a spermicidal lubricant. The statement is required by FDA's November 1993 guidance on condom labeling entitled "Information for Condoms with a Spermicidal Lubricant 510(k) submission." The requested, shortened version would read:

"This condom contains a spermicide, Nonoxynol-9, which can reduce the number of active sperm if semen spill outside the condom, although the decreased pregnancy risk is not known. For maximum effectiveness, this condom should be used with a vaginal spermicide."

99P-2852

CP1

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### B. Statement of Grounds

The shortened version of the statement required on condoms with spermicidal lubricant is requested because the increased amount of required information on condom labeling makes it difficult if not impossible to present all the required information in a readable form. The shortened version of this statement will allow easier-to-read condom labeling and thus be of benefit to the consumer.

The shortened version of the statement contains all of the essential information which is in the presently required version of the statement and is accurate and not misleading.

The FDA has already approved a slightly different shortened version of this statement based on the petition of another condom manufacturer. See PDN1 (page 2) in Docket 98P-0109. The version requested here should be equally acceptable. In the recent case of *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20 (D.D.C. 1997), the court states that "[d]isparate treatment of functionally indistinguishable products is the essence of the meaning of arbitrary and capricious." Thus, fairness requires that this version of the statement be approved as well.

### C. Environmental Impact

Categorical exclusion is claimed under Section 25.30(h) of the regulations.

### D. Economic Impact

Economic information will be submitted if requested by the Commissioner.

### E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes

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representative data and information known to the petitioners  
which are unfavorable to the petition.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Richard S. Morey', written in a cursive style.

Richard S. Morey

Counsel for Ansell  
Healthcare Inc.